

REMARKS

Claims 1-8 and 16-19 are pending.

Formal drawings are submitted herewith.

It is respectfully submitted that the present response presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the following remarks is requested.

I. The Rejection of Claim 5 under 35 U.S.C. 112

Claim 5 stands rejected under 35 U.S.C. 112 as non-enabled. The Examiner states that claim 5 claims retention of >90% activity under conditions at 25°C and <90% activity under the same conditions at 30°C. The Examiner alleges that there is "apparently no teaching of the activity of the enzyme under the conditions in the instant specification." The Examiner states that he has examined page 5 of the specification, as requested by Applicants in their prior response, and the Examiner does not find "any mention of these conditions." This rejection is respectfully traversed.

Quoting directly from page 5 of the specification:

Stability was tested by incubating 40 NU/ml of amylase in a solution of 3 g/l of the A/P model detergent described above, at pH 10.5 and 6°dH (German hardness, Ca:Mg 2:1). After the incubation, the residual activity was measured by Phadebas at pH 7.3. **The results were 95 % residual activity after incubation at 25°C, and 87 % at 30°C.**

(Emphasis added.)

Based on the above direct quote, Applicants respectfully submit that the Examiner's statement that he does not find "any mention of these conditions" at page 5 is plainly incorrect.

Moreover, the asserted rejection is an enablement rejection. The test for enablement is whether the written description permits one skilled in the art to practice the claimed invention without undue experimentation. In this regards, an artisan, once apprised by the claimed invention, including the claim language itself which virtually mirrors the language of the specification on page 5, would clearly be able to carry out the recited test to determine if the enzyme meets the recited conditions. Furthermore, the Examiner has not provided any contrary reasoning or evidence which would refute that an artisan would not be able practice claim 5.

Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The 102 and 103 Rejections Over Mitsugi et al. and Boyer et al.

Claims 1-7 and 16 are rejected under 35 U.S.C. 102 as being anticipated by Mitsugi et al. (US Pat. No. 4,022,666) or Boyer et al. (US Pat. No. 4,061,541). Claims 8 and 17-19 are rejected under 35 U.S.C. 103 as obvious over Mitsugi et al. or Boyer et al. The Examiner contends that Applicants' assertion that the claimed enzymes are patentably distinct over the enzymes in the cited references is not sufficient to overcome the rejections, and, citing *In re Best, Bolton and Shaw*, 195 USPQ 430, 433 (CCPA 1977), the Examiner states that the PTO can require that Applicants prove that the prior art does not necessarily or inherently possess the characteristics of the claimed product.

Applicants attempted to make the comparison requested by the Examiner to prove that the claimed enzymes are patentably distinct over the enzymes in the cited references. As discussed below, Applicants efforts revealed that the cited references are not proper 102 or 103 references because they both lack enablement.

Mitsugi et al.

With respect to Mitsugi et al. (U.S. Patent No. 4,022,666), Applicants attempted to obtain strain FERM P376. As shown in Exhibit A, strain FERM P376 has been withdrawn by the depositor. Accordingly, it is respectfully submitted that Mitsugi et al. (U.S. Patent No. 4,022,666) is not prior art because it is not an enabling reference as *Bacillus subtilis* AJ-3255 (FERM P376) is not available. See *In re Donohue*, 226 USPQ 619 (Fed. Cir. 1985) ("even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice if it was not enabling"); see also *Beckman Instru., Inc. v. LKB Produkter AB*, 13 USPQ2d 1301 (Fed. Cir. 1989) ("In order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method.")

Boyer et al.

With respect to Boyer et al., Applicants obtained a sample of the strain NRRL-3881 and attempted to express the amylase to obtain a sample for comparison. As discussed in the accompanying declaration of Preban Nielsen, despite following very sensitive procedures in the art for detecting alpha-amylase activity, Applicants were unable to identify a detectable amount of alpha-amylase activity. Accordingly, Dr. Nielsen concludes that NRRL does not produce an alpha-amylase. This information is also consistent with the classification of NRRL as *Bacillus halodurans* (which is known not to produce an alpha-amylase) and the PCR reaction performed (in which a PCR reaction using two degenerated primers that recognize the gene of known alpha-amylases from *Bacillus*, did not detect a product with DNA from NRRL 3881.

Accordingly, Applicants maintain that claimed enzymes are patentably distinct from Boyer et al. Moreover, it is respectfully submitted that Boyer et al. is also not an enabling reference as one skilled in the art is not able to obtain the amylase from NRRL-3881. See *In re Donohue*, 226 USPQ 619 (Fed. Cir. 1985); see also *Beckman Instru., Inc. v. LKB Produkter AB*, 13 USPQ2d 1301 (Fed. Cir. 1989).

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102/103. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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